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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,762	05/14/2001	Cecilia Larsson	1547/00275	7301

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EXAMINER

MATTHEWS, WILLIAM H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/743,762	Applicant(s) LARSSON ET AL.	
	Examiner William H. Matthews (Howie)	Art Unit 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 December 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
     If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:  
         1. ☐ Certified copies of the priority documents have been received.  
         2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
         3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
     \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
     a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                            | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)        | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)   |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ | 6) <input checked="" type="checkbox"/> Other: <i>See Continuation Sheet</i> . |

Continuation of Attachment(s) 6). Other: Translation Copy of JP 2631890B2.

## **DETAILED ACTION**

### ***Response to Arguments***

Applicant's arguments with respect to claims 31-53 have been considered but are moot in view of the new ground(s) of rejection.

Please note that Cassidy et al. US PN 6,280,474 qualifies as prior art because of priority claimed to application numbers 09/004,550 (January 8, 1998), 08/833,874 (April 10, 1997), and 08/781,012 (January 9, 1997). Applicant's earliest priority date is July 13, 1998.

### ***Specification***

1. The specification is objected to because of references listed in the specification and not in an information disclosure statement. All references listed in the specification should be included in an information disclosure statement. Correction is required. See MPEP § 608.01(b).

### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 31-55 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 31 recites the limitation "a phosphoglyceride" which is not found in the specification. The specification provides support for a particular phosphoglyceride (phosphatidyl choline), but does not disclose the invention to be used with any phosphoglyceride.

Claims 32-52,54,55 depend from claim 31 and therefore contain the same new matter limitation "a phosphoglyceride".

Claim 53 recites the limitation "said tissue-promoting factor is a fragment thereof wherein said fragment retains biological activity" which is not found in the specification or claims as originally filed.

5. Claims 32-55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-52,54,55 recite a "preparation" which is not consistent with the composition recited in claim 31.

Additional, claims 43-44 are indefinite because it is unclear whether glycosaminoglycan and sodium hyaluronic acid refers to previously recited hyaluronic acid or another element.

Claims 46-48 are indefinite because it is unclear whether calcium phosphate refers to calcium phosphate granules previously recited or a new element.

Claim 53 is indefinite because claim 53 depends on claim 53.

Claims 42 and 54 recites the limitation "water or some other water based liquid" in lines 1-2 of each claim. There is insufficient antecedent basis for this limitation in the claim.

Claim 55 recites the limitation "said glycosaminoglycan" in line 1. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 31-40,43-50,52,53,55 are rejected under 35 U.S.C. 103(a) as being unpatentable over NGK Spark Plug Co Ltd (JP 2198560) in view of Cassidy et al. US PN 6,280,474. Please note the supplied translation of JP 2198560.

8. NGK discloses in pages 6-16 (of the translation) a bone composition comprising the claimed forms of calcium phosphate, lipids, biologically active agents such as tissue promoting factors, and phosphatidyl choline or sphingomyeline. NGK lacks the express written disclosure of including a glycosaminoglycan such as sodium hyaluronic acid or that the calcium phosphate granules have a diameter of 0.05-5mm. Cassidy et al.

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teaches in columns 11-12 bone implant compositions comprising calcium phosphate granules having a diameter of 0.05-5mm and sodium hyaluronate to aid in shape retention of the implant during rehydration. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the device disclosed by NGK by using calcium phosphate granules having a diameter of 0.05-5mm and sodium hyaluronate to aid in shape retention of the implant during rehydration.

9. Claims 41,42,51, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over NGK Spark Plug Co Ltd (JP 2198560) in view of Cassidy et al. US PN 6,280,474 as applied to claims 31 and 40 above, and in further view of Larsson et al. US PN 5,196,201.

The bone composition taught by NGK as modified by Cassidy et al. meets the structural limitations of claims 41,42,51, and 54 but lacks the express written disclosure of the lipid in a lamellar floating crystalline phase and the specific ratios between the lipid to water based liquid and calcium phosphate granules to lipid. Larsson et al. teaches in lines 61 of col. 6 through line 31 of column 8 a bone composition having the specific ratios and lipid in a lamellar floating crystalline phase in order to provide a desired consistency. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the composition disclosed by NGK, as modified by Cassidy et al. above, to further included the specific ratios and lipid phase of claims 41,42,51, and 54 in order to provide a desired consistency.

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### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Matthews (Howie) whose telephone number is 703-305-0316. The examiner can normally be reached on Mon-Fri 7:00-4:30 (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are (703)



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308-2708 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



WHM  
April 4, 2003



CORRINE McDERMOTT  
SUPERVISORY PATENT EXAMINER  
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